

Exhibit 2

1 PRESENT ON BEHALF OF THE PLAINTIFFS:
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4 Mount Pleasant, South Carolina 29464
5 401.457.7700
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17
18 PRESENT ON BEHALF OF THE DEFENDANT:
19

20 TUCKER ELLIS, LLP
21 950 Main Avenue, Suite 1100
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23 216.592.5000
24 BY: MATTHEW P. MORIARTY, ESQ.
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1 that's just a very sort of nonspecific term related
2 to any aspect of a surgical procedure where there
3 was some question raised.

4 Q. So the question would be raised as to
5 whether the doctor was at fault with a complication
6 of one kind or another?

7 A. Yes. Typically these are all, yeah,
8 single patient/one doctor type cases and
9 situations.

10 Q. Are all the opinions that you intend to
11 offer contained in the general report that you
12 issued?

13 MR. MORIARTY: Objection to form. Go
14 ahead.

15 Q. Regarding general opinions.

16 MR. MORIARTY: Objection. Go ahead.

17 A. Well, I will answer all the questions to
18 the best of my ability. If you ask me things
19 outside the context of things I have already
20 written, I will certainly offer those opinions, but
21 I think most of my opinions will be consistent with
22 what has been written down and produced.

23 Q. Fair enough. Are your opinions
24 objective?

1 MR. MORIARTY: Objection.

2 A. Yes, I believe my opinions are
3 objective. They are opinions to my best ability to
4 give an opinion based on my own training and to my
5 best degree of medical certainty, if you will.

6 Q. And are your opinions unbiased?

7 MR. MORIARTY: Objection. Go ahead.

8 A. I think my opinions are unbiased.

9 Q. When you prepared -- did you prepare the
10 report yourself?

11 A. I did.

12 Q. And how did you decide what to include
13 and what not to include in your report?

14 MR. MORIARTY: Objection. Go ahead.

15 A. Well, as you can guess, you know, there
16 is a voluminous amount of information that can go
17 into a report like this and there is, you know,
18 years and years of documents, scientific papers,
19 research articles, journal articles and abstracts,
20 et cetera. So, you sort of pick and choose and you
21 try to get a broad array of Level 1 evidence that
22 reflects good science. That's what I try to
23 include.

24 Q. Did you receive materials from defense

1 counsel as you were preparing your general report?

2 A. Well, there was conversations and
3 e-mails about certain papers and abstracts and
4 journals and such and things I looked up on my own.

5 Q. Did you do any kind of literature search
6 on your own?

7 A. Yes. I do literature searches all the
8 time, and I certainly, you know, do literature
9 searches consistently in my occupation, being an
10 academic at the University of Chicago; and
11 certainly I did some literature search and looked
12 back at some of these manuscripts in the
13 preparation of my report.

14 Q. Did you search for particular products,
15 for example?

16 A. Well, in general just we started
17 obviously with sort of pelvic organ prolapse, and
18 I'm familiar with a lot of literature just because
19 I have been reviewing it and I review the Journal
20 of Urology and Urology and Neurourology and
21 Urodynamics. But again, and I looked at some
22 case-specific things regarding the ProLift and, you
23 know, the Ethicon products.

24 Q. Did you receive any internal Ethicon

1 years, so I couldn't go back and quantify the
2 number of cases I've done. I've done, you know,
3 well into the thousands in terms of pelvic floor
4 procedures between prolapse and slings and
5 sacrocolpopexies.

6 So, I couldn't give you the denominator
7 and I couldn't give you the numerator unless I went
8 back and contacted the individual every patient.
9 So, again, you asked me for a specific number, and
10 I wasn't able to provide that.

11 Q. What Ethicon prolapse products are you
12 currently using?

13 A. So, I currently primarily used the TVT,
14 which is a sling product, and the TVT obturator,
15 which again is a sling product but the sling is
16 placed in a slightly different fashion. It's not
17 retropubic but it goes through the obturator
18 foramen.

19 Q. So you are currently not using any
20 Ethicon products to treat prolapse?

21 A. I'm not as far as I know. I think many
22 of them are off the market. I'm not sure they are
23 available, but no, I'm not.

24 Q. Do you use Gynemesh PS in your abdominal

1 sacrocolpopexies?

2 A. I used Gynemesh PS for my
3 sacrocolpopexies for a long time. Sometimes I'm at
4 the whim of the University of Chicago. They
5 sometimes they get other products in, so sometimes
6 it's not up to me.

7 Currently the product they have for that
8 application is the AMS product called IntePro, but
9 again, unfortunately, sometimes the doctors don't
10 have any ability to -- to -- weren't involved in
11 the decision-making.

12 Q. How many Prolift procedures have you
13 performed over your career, approximately?

14 A. So, just to clarify, there is total
15 Prolift, there is anterior Prolift and posterior
16 Prolift, so there is sort of three. You want an
17 estimate based on all those procedures put
18 together?

19 Q. Why don't you give me all and then break
20 them down as to how many of each.

21 A. So, I would -- roughly, again it's a
22 rough guesstimate. This goes back again ten years
23 or so. Probably several hundred of -- probably
24 several hundred of all of them, and then the

1 breakdown would be probably 50 percent anterior
2 Prolift, probably 45 percent total Prolift and a
3 very smaller -- a much smaller percentage,
4 5 percent or less of the posterior Prolift.

5 Q. Have you published any peer-reviewed
6 articles regarding using vaginal mesh for prolapse
7 repairs?

8 A. Yes.

9 Q. What are those articles?

10 MR. MORIARTY: Objection.

11 A. Again, I mean, I think my CV -- do we
12 have my CV here? I would have to show you. I
13 don't remember the exact citation.

14 Q. Did you bring your CV?

15 A. I don't think I have a copy of my CV.

16 MR. MORIARTY: We produced it with the
17 report and reliance list.

18 BY MS. THOMPSON:

19 Q. Okay. And do you treat mesh
20 complications in your practice?

21 A. Absolutely. More complications than I
22 care to.

23 Q. What are the most common mesh
24 complications that you treat in your practice?

1 A. So, there is a variety. There is
2 complications of exposures or extrusions where the
3 mesh is sort of exposed and through the vaginal
4 wall, and there is some pain complications that
5 patients see which may or may not always be related
6 to the mesh in any fashion necessarily. But
7 patients come in with again after pelvic organ
8 prolapse surgeries complaining of pain, and
9 obviously the most common, I guess, is a recurrence
10 of the prolapse, where they are coming in, they
11 have already had a procedure and now it's failed
12 and they need additional surgery.

13 Q. What type of pain complications do you
14 treat related to mesh?

15 A. Well, as I said, I don't know if you can
16 sometimes discern what's related to mesh and what
17 isn't, but patients come in and they have pain in
18 their pelvic floor, in their vaginal canal area,
19 and we treat it. We treat it in combination with
20 our physical therapists, and also we have some
21 wonderful pain specialists. So, we treat all
22 gamuts of pain with or without or whether or
23 whether they have not had any kind of mesh
24 procedure.

1 causing the pain on any individual patient.

2 Q. I want you to answer my question.

3 Is it your testimony considering the
4 factors, the rate, the severity, the responsiveness
5 to treatment, the permanence, that there is no
6 difference between mesh repairs and native tissue
7 repairs regarding pain?

8 MR. MORIARTY: Same objection. Go
9 ahead.

10 A. Again, there is -- I mean, it depends on
11 what we are talking about in terms of the pain.
12 It's just such a broad statement. I think in
13 general, yeah, I think it's probably the same, but
14 I also don't think it is a good question because
15 it's so broad.

16 Q. Do you hold yourself out as an expert in
17 medical device design, Dr. Bales?

18 A. You know, it's funny. Whenever I've
19 taken depositions -- you asked me earlier -- people
20 ask are you an expert. And so, again, I'm a
21 board-certified urologist, so the default answer is
22 always, well, I'm an expert as a urologist, right?
23 So, if you ask me if I'm an expert in other things
24 and you sort of think, well, I'm not

1 board-certified in other areas, I'm a
2 board-certified urologist, but I'm an expert in
3 things that I do very commonly and things that I'm
4 very experienced in.

5 So, again, medical devices, if the
6 medical device is that I've used and very familiar
7 with and I've held in my hand and I've placed into
8 patients and I have done their surgeries, then yes,
9 I guess I'm considered an expert.

10 Q. Have you ever designed a medical device?

11 A. I have not.

12 Q. Are you a biomaterials expert?

13 A. Again, sort of the same answer to the
14 previous question. It depends on what biomaterials
15 I guess we are talking about. But if we are
16 talking about biomaterials that I'm familiar with,
17 including some of the meshes and things that I've
18 implanted in patients and held in my hand and have
19 done hundreds of times, then I guess I'm certainly
20 very familiar and a lot more knowledgeable than 99
21 percent of people.

22 Q. Have you ever looked at an explanted
23 mesh device histologically?

24 A. So, yes, I suspect I have, and I've

1 certainly seen pictures of the histologic
2 presentations, and yes, I'm sure I have been in our
3 pathology department at least a couple times and
4 looked at some of these things. But, you know, it
5 will be very difficult for me to describe the
6 histologic appearance.

7 Q. So you would not consider yourself an
8 expert in pathology?

9 A. I'm very knowledgeable about pathology,
10 but I'm certainly not an expert and be able to
11 describe the specific pathologic features that a
12 pathologist, a board-certified pathologist would be
13 able to do.

14 Q. Are you an expert in regulatory affairs?

15 A. That's such a broad thing, what
16 regulatory affairs are, that again I guess I can't
17 say I'm any kind of expert in regulatory affairs.
18 I'm not sure even what that means.

19 Q. How about industry standards for
20 warnings?

21 MR. MORIARTY: Objection, form.

22 A. So, an expert in industry, you are
23 asking me if I'm an expert in industry standards of
24 warnings.

1 So, again, I'm not -- I'm not aware of
2 what those standards may be, so I guess I'm not an
3 expert in it.

4 Q. We are going to go through your report.
5 I'm going to ask you some questions about some of
6 your opinions contained in the report. If you want
7 to follow along, you are welcome to.

8 On Page 3 --

9 A. Can I just -- let me make sure I'm just
10 working off the same copy. You said you gave it
11 that. Was that Exhibit 2? Was it Exhibit 2?

12 Q. Exhibit 2, correct.

13 A. Can I have it just to make sure? Go
14 ahead. Thank you.

15 Q. At the bottom of Page 3 you start out
16 talking about sacrocolpopexy and then you also talk
17 about uterosacral ligament suspensions and
18 sacrospinous ligament fixations. Do you perform
19 either of those procedures?

20 A. Yes.

21 Q. When was the last time you performed
22 either one and which one?

23 A. A long time ago, a number of years ago,
24 five years ago.

1 aware of as I sit here right now.

2 Q. So I'm curious why you would say
3 unfortunately these procedures have a success rate
4 of only 60 percent at two years when Prolift is no
5 better. Is that an objective and unbiased
6 statement in your report?

7 MR. MORIARTY: Objection, form. Go
8 ahead.

9 A. So, again, the statement reads that
10 unfortunately, these two procedures had a success
11 rate of 60 percent in two years. So, that's --
12 again, that's a direct citation from that paper, so
13 I don't know how more unbiased you can be, right?
14 I'm citing this paper and putting in the success
15 rate. So, I'm only just rehashing what again is in
16 the medical literature.

17 Q. Does that paper say "unfortunately the
18 success rate of 60 percent"?

19 A. So you are concerned about the
20 "unfortunately"?

21 Q. Well, I just didn't notice an opinion in
22 your report that said "Unfortunately, Prolift only
23 has a 60 percent success rate."

24 A. Prolift isn't perfect either, and again,

1 that's not the sentence. But I guess if I had said
2 "The Prolift repairs have a success rate of X," I
3 guess I could have put "unfortunately" in front of
4 that. It's unfortunate that any surgical procedure
5 is less than 100 percent, so I guess --

6 Q. But you didn't put that in your report,
7 though, did you?

8 A. It looks like I didn't.

9 Q. In the paragraph -- and unfortunately,
10 we don't have time to go through all the
11 literature, but I do want to highlight some of it.

12 So, in your paragraph, your short
13 paragraph about colporrhaphy --

14 A. Can you tell me where that is?

15 Q. It is on Page 4.

16 A. Okay.

17 Q. You state that high rates of recurrence
18 of 30 percent or more have been reported with
19 colporrhaphy, particularly in the anterior
20 compartment. What's the recurrence in the
21 posterior compartment in the literature?

22 A. I think that again, like most of these
23 things that we are going to be discussing, there is
24 going to be various series where the numbers are

1 going to vary slightly, but it's probably 20 to 30
2 percent, especially if you follow these patients
3 long enough.

4 That's actually, unfortunately, as you
5 know, just not to lecture, but that's actually,
6 unfortunately, one of the problems with our medical
7 literature, is that a lot of these series, the
8 followup is relatively short, so there is not
9 enough papers looking at patients over a long
10 enough period of time where the recurrence rates
11 obviously go up, unfortunately.

12 Q. So it's your testimony that the failure
13 rate of posterior -- native tissue posterior
14 repairs is 20 to 30 percent?

15 A. Yes.

16 Q. Are you aware of any literature where
17 posterior Prolift improves the failure rates in a
18 posterior repair over native tissue?

19 A. I think -- I think some of the
20 literature that's out there shows it to be
21 equivalent. Again, I don't think there is a lot of
22 great literature on long-term outcomes with the
23 Prolift, but I don't know if it's better, to answer
24 your question.

1 Q. So I want to look at some of the --
2 before we look at some of the efficacy literature,
3 let's mark this as the next exhibit.

4 (Bales Exhibit 7 was marked for
5 identification.)

6 BY MS. THOMPSON:

7 Q. You are certainly aware that some
8 doctors feel that mesh complications are more
9 serious than native tissue repair complications,
10 correct?

11 MR. MORIARTY: Objection, form.

12 A. I suspect there is some doctors who feel
13 that way, sure, definitely.

14 Q. Do you know Linda Cardozo?

15 A. No.

Q. Do you know her name?

17 A. I know the name.

18 Q. I'm going to show you an e-mail from
19 2005. When was the Prolift marketed, introduced
20 into the market?

21 A. I think the end of 2005. I don't
22 remember exactly. You might know better than me.
23 I want to say it was sometime in 2005, towards the
24 end of 2005.

1 then say but I want to get started using it. So
2 that's why, again, it is hard for me to interpret
3 this.

4 Q. Was there any efficacy data when you
5 began using that Prolift device in 2006?

6 A. There is never -- any new procedure we
7 do, there is never any real good efficacy data on
8 any new procedure.

9 Q. I want to go over some of the literature
10 on the colporrhaphy and the efficacy, and I'm
11 using -- I'm going to start with the Weber article
12 that you cited in your report; and you are aware,
13 Dr. Bales, that the Weber article from 2001 was
14 re-analyzed with modern definitions of prolapse and
15 success by Chmielewski, correct?

16 A. Yes.

17 Q. I'm curious why you cited the 2001 Weber
18 article rather than the 2011.

19 A. So, I guess if that's a question, again,
20 it's impossible to cite every article that's out
21 there, so I picked certain ones.

22 MS. THOMPSON: And if you could mark
23 this as Exhibit No. 8. I just have two copies
24 of this, sorry.

1 (Bales Exhibit 8 was marked for
2 identification.)

3 BY MS. THOMPSON:

4 Q. Are you familiar with this paper,
5 Dr. Bales?

6 A. Yes.

7 Q. And let's just go to the conclusions,
8 and could you read the last paragraph for us.

9 A. Would you like me to read the entire
10 last paragraph?

11 Q. Um-hmm?

12 A. Starting "In conclusion"?

13 Q. Um-hmm.

14 A. "In conclusion, this study provides
15 further evidence that success after prolapse
16 surgery depends heavily on the criteria that are
17 used to define treatment success. In the
18 frequently cited study by Weber, et al., when
19 strict anatomic criteria were used, success was
20 low. However, when contemporary, clinically
21 relevant criteria for success were used, treatment
22 success was considerably better, with only 11
23 percent of subjects experiencing anatomic
24 recurrence beyond the hymen, 5 percent of subjects

1 experiencing symptomatic recurrence, and no
2 subjects requiring surgery for recurrence or
3 complications at one year.

4 "Given this and the excellent safety
5 profile of traditional vaginal prolapse surgery,
6 we conclude that anterior colporrhaphy that is
7 performed in conjunction with other native tissue
8 repairs is appropriate as a primary treatment of
9 symptomatic anterior vaginal prolapse."

10 Q. And my question is, why did you cite the
11 Weber paper in 2001 when this paper is more recent
12 and more authoritative?

13 MR. MORIARTY: Objection, form and
14 asked and answered. Go ahead.

15 Q. Well, let me just say, is your -- is
16 your -- the reason that you didn't use this paper
17 is you just can't cite everything? I think that
18 was your answer before. Is that it --

19 A. Yeah --

20 Q. -- why you chose the old paper?

21 A. Yeah, I apologize. I chose -- I tried
22 to choose a appropriate synopsis of a variety of
23 different things. I'm sure there are other papers
24 that I missed that might be more current or what

1 have you. But again, there is a lot of literature
2 that's out there. I had to cite certain things.

3 Q. And you will certainly agree with me
4 that a 5 percent symptomatic recurrence and no
5 subjects requiring additional surgery is very
6 different from the recurrence of 30 percent or more
7 that you cite in your paper, right?

8 A. So you are asking if 30 is different
9 than 5, and the answer is yes, 30 is different than
10 5.

11 Q. And you believe that you reported
12 objectively on the success rates with colporrhaphy?

13 A. Yes. I think this paper, actually, this
14 later information actually is somewhat of an
15 anomaly; and I think most -- most papers and again,
16 there is, you know, lots of data and lots of
17 studies that aren't cited here, would suggest that
18 the number is higher than 5 percent. And again,
19 there is going to be a variety based on the paper.

20 Q. Okay. Well, let's go to one of the
21 other papers that you cited and Fed Ex'd. I
22 thought this one was apparently really important,
23 and I just have two copies of this one, I'm sorry
24 to say.

1 We will mark that as the next exhibit,
2 9, and you are familiar with this paper because you
3 cite it in your paper, in your report, right?

4 A. Yeah. Peter --

5 MR. MORIARTY: It's so big you can
6 hardly miss it.

7 MS. THOMPSON: The first paper was
8 that -- I have two of these that are large
9 size. The first one was from Duke. I thought
10 they just thought it was from Duke that it was
11 important.

12 THE WITNESS: These guys work with us.
13 They are part of the University of Chicago
14 now, Peter Sand and Roger Goldberg and Janet
15 Tomezsko.

16 (Bales Exhibit 9 was marked for
17 identification.)

18 BY MS. THOMPSON:

19 Q. I actually want to turn your attention
20 to that discussion of this paper --

21 A. Okay.

22 Q. -- by Dr. Shull. Do you know Dr. Shull?

23 A. I don't.

24 Q. Have you seen Dr. Shull cited in Ethicon

1 series of over 300 women" --

2 MR. MORIARTY: I'm sorry. Can you
3 please tell us what you are reading from?

4 MS. THOMPSON: Several factors are
5 related to long-term outcome.

6 MR. MORIARTY: We need to know where
7 you are reading from.

8 MS. THOMPSON: I'm telling you. In
9 the comments section it says several factors
10 are related to long-term outcome, and I'm
11 reading from number one.

12 BY MS. THOMPSON:

13 Q. "In our most recent series of greater
14 than 300 women in whom we specifically repaired the
15 transverse portion of the pubocervical fascia,
16 along with other defects, the rate of anterior
17 compartment persistence or recurrence was 7 percent
18 for prolapse halfway to the hymen and 2 percent for
19 prolapse to the hymen. We used no mesh."

20 You will agree with me that a success
21 rate of 7 percent halfway to the hymen and 2
22 percent for prolapse to the hymen with a native
23 tissue repair is significantly less than the 30
24 percent that you cited in your expert report,

1 correct?

2 MR. MORIARTY: Objection, form.

3 A. I think 30 percent is a more accurate
4 representation of what the experience is nationwide
5 for sure, as you just read.

6 Dr. Shull is a very accomplished
7 urogynecologist who I don't know personally, but
8 he is citing his own work, and he obviously gets
9 excellent results with his native tissue repair.

10 I'm not sure how long these patients
11 were followed, but he cites 7 percent in his
12 experience, and 7 percent is a lower number than
13 30 percent.

14 MS. THOMPSON: I've just handed
15 another paper. Would you mark this as Exhibit
16 No. 9.

17 MR. MORIARTY: 10.

18 (Bales Exhibit 10 was marked for
19 identification.)

20 BY MS. THOMPSON:

21 Q. Dr. Bales, are you familiar with
22 Exhibit 10, a paper by Funk and Visco?

23 A. Yes.

24 Q. And this paper looked at 27,809 anterior

1 prolapse surgeries. The 5-year risk of surgery for
2 recurrent prolapse was similar between vaginal mesh
3 and native tissue groups with 10.4 percent
4 recurrent with mesh and 9.3 recurrent with native
5 tissue. You will agree that those numbers are
6 significantly less than the 30 percent that you
7 cited in your expert report, correct?

8 A. Yes.

9 Q. And that there was -- in this paper of
10 27,000-plus patients, there was no difference
11 between mesh and native tissue repairs, correct?

12 A. Yes, it looks like they are, right,
13 essentially similar.

14 MS. THOMPSON: And Exhibit No. 11.

15 (Bales Exhibit 11 was marked for
16 identification.)

17 BY MS. THOMPSON:

18 Q. Are you familiar with this paper by
19 Dr. Oversand?

20 A. Yes.

21 Q. And Dr. Oversand had a satisfaction rate
22 of 94 percent of patients with native tissue
23 anterior repairs and a 5-year reoperation rate of
24 2.6 percent in one group and 8.9 percent in the

1 other group and concluded that POP surgery using
2 native tissue repair entails low reoperation rates
3 with excellent subjective and objective results and
4 should be the primary -- should be the first choice
5 in treating primary POP providing use of adequate
6 surgical technique as was published in 2013.

7 That's certainly different from what you
8 cited in your expert report, correct?

9 MR. MORIARTY: Objection, form.

10 A. Again, the numbers are lower in this
11 paper in terms of the recurrence rates, yes.

12 MS. THOMPSON: And Exhibit No. 12.

13 (Bales Exhibit 12 was marked for
14 identification.)

15 BY MS. THOMPSON:

16 Q. Are you familiar with this paper,
17 Dr. Bales?

18 A. Yes.

19 Q. And this is the three-year followup on
20 Dr. Iglesia's original Prolift study, correct?

21 A. Yes. I'm just trying to see if they are
22 all Prolift people, to make sure on the methods.

23 Yes, okay.

24 Q. And you are aware that this study was

1 halted prematurely because of 15.6 percent mesh
2 erosion rate which exceeded their predetermined
3 limit, correct?

4 A. Yes, it is prematurely halted.

5 Q. And -- but they continued to follow the
6 patients for efficacy, correct?

7 And these authors concluded that there
8 was no difference in three-year cure rates when
9 comparing patients undergoing traditional vaginal
10 prolapse surgery without mesh with those undergoing
11 vaginal colpopexy repair with mesh, correct?

12 A. Right. You can read their conclusion.

13 They saw no difference.

14 Q. And this paper wasn't included in your
15 expert report, was it?

16 A. I don't think so.

17 Q. And it is still your opinion that
18 colporrhaphy has a recurrence of over 30 percent
19 and that mesh repairs are preferable?

20 MR. MORIARTY: Objection, form.

21 A. It's my opinion that, yeah, anterior
22 recurrence rates are as high as 30 percent.

23 Q. Or you said 30 percent or more, not as
24 high as 30 percent.

1 Q. And that would be consistent also with
2 the paper we just looked at previously, at the Abed
3 paper, correct?

4 MR. MORIARTY: Objection. Are you
5 just talking about the dyspareunia rate?

6 MS. THOMPSON: Just the dyspareunia.

7 Sorry.

8 A. Yes.

9 Q. If we go to the Jacquetin 2013 paper --
10 we will mark this one too, 17. I think you are
11 familiar with this one because it is cited in your
12 expert report, correct?

13 A. Correct.

14 (Bales Exhibit 17 was marked for
15 identification.)

16 BY MS. THOMPSON:

17 Q. And this Jacquetin paper with the
18 followup of the TVM, total transvaginal mesh
19 series, this is the one that your chart was derived
20 from, correct?

21 A. Yes.

22 Q. And in this paper, in the results
23 section of the abstract, Dr. Jacquetin reports 16
24 percent with mesh exposure for which 8 resections

1 needed to be performed, 7 exposures still ongoing
2 at the 5-year endpoint, all asymptomatic, correct?
3 I'm reading that correctly?

4 A. You are reading that correctly, yes.

5 Q. And only 33 out of 61, 54 percent,
6 sexually active patients at baseline remained so at
7 5 years in his study, correct?

8 A. That's correct.

9 Q. And de novo dyspareunia was reported by
10 10 percent, correct?

11 A. That's correct.

12 Q. And you are aware that Jacquetin also
13 published a paper based on the experience titled
14 "Complications of Vaginal Mesh"?

15 A. Do you have it? Did you want to go over
16 it?

17 Q. I need a helper.

18 A. Maybe this young fella.

19 MS. THOMPSON: It is just a short
20 paper. I do have one additional copy, and we
21 will mark that as Exhibit 18.

22 (Bales Exhibit 18 was marked for
23 identification.)

24

1 BY MS. THOMPSON:

2 Q. Do you need a moment to look at that, or
3 are you familiar with this paper?

4 A. Yeah, I'm familiar. I'm skimming it
5 over, but if I need more time I won't answer your
6 question and I will ask for a few more minutes, but
7 you can ask your question.

8 Q. This paper is based on Jacquetin's
9 experience with removal of 160 explant -- implants,
10 correct?

11 A. I will need just a second to confirm
12 that number.

13 Yeah, I mean, it seems that he is just
14 discussing more broadly everything about some of
15 his experiences and citing some other work, but
16 then on Page 895 he discusses that the French
17 experience is 160 implants that were removed by his
18 group, yep.

19 Q. And under the complications he lists
20 infections, correct, on Page 894?

21 A. Correct.

22 Q. And he lists exposures and erosions,
23 correct?

24 A. Yep.

1 Q. And he lists retractions, correct?

2 A. That's correct. We are reading, yes,
3 those are the three things.

4 Q. And he describes the average shrinking
5 of 25 to 30 percent in experimental surgery, and it
6 may reach 40 percent of the initial surface of the
7 implant in patients after surgery.

8 MR. MORIARTY: Is that a question?

9 Q. And therefore, many surgeons will use
10 large implants to cover defects and anticipate
11 scarring, shrinkage and puckering. Is that what
12 Dr. Jacquetin describes in this paper?

13 MR. MORIARTY: Objection, form.

14 Q. Did I read it correctly?

15 A. I think that bullet point you read
16 exactly, so that's what he has written here, yeah.

17 Q. And we will talk about your opinions on
18 shrinkage in a minute, but at least Dr. Jacquetin
19 listed that retraction as a complication of the
20 mesh devices he studied, correct?

21 A. Sure, and you left out -- right, and he
22 describes on a rat's abdominal wall and then he is
23 guesstimating based -- he says it may reach
24 40 percent on patients. So, it sounds like at

1 least on the experimental side it's on the rat's
2 abdominal wall, but you read the rest of the
3 sentence accurately.

4 Q. So, you think when he says -- sorry.
5 So, you think when he says, therefore, many
6 surgeons will use large implants to cover defects
7 and anticipate scarring, shrinkage and puckering he
8 is talking about rat surgeons?

9 MR. MORIARTY: Objection, form.

10 MS. THOMPSON: Well, I'm just asking
11 if that's what he meant, what he said.

12 MR. MORIARTY: You asked him if you
13 read that exactly, and you didn't. You
14 skipped the part about the rats, so he was
15 just pointing out what you skipped.

16 MS. THOMPSON: I don't think I did.

17 MR. MORIARTY: That's why I objected
18 to form. You skipped the part about the rats.

19 MS. THOMPSON: Well, I didn't intend
20 to skip.

21 BY MS. THOMPSON:

22 Q. You don't think the second sentence is
23 applying to rats, do you, Dr. Bales?

24 A. Well, the second sentence specifically

1 says patients; the first sentence definitely says
2 rats. So, I guess that was the only clarification.

3 Q. So you think the 40 percent would refer
4 to patients, human patients, right?

5 A. Well, again, I mean, he is not citing
6 any specific study here. It sounds like he is
7 surmising it may reach. I don't --

8 Q. But he is talking about humans, right?

9 A. He says in patients, so I would assume
10 that means patients.

11 Q. And when he says many surgeons will use
12 large implants to cover defect and anticipate
13 scarring, shrinking and puckering, he is talking
14 about human patients also; agree?

15 A. I suspect, although again, it's a very
16 general statement, and I'm not sure which surgeons
17 he is referring to or anything, how large. I mean,
18 it's just kind of a very general statement. I
19 imagine he is referring to surgeons operating on
20 humans. I don't want to over-infer.

21 Q. Okay. I want appreciate that.

22 (Mr. Jake Plattenberger entered the
23 deposition proceedings.)

24 MR. MORIARTY: Can we help you?

1 MR. DAVIS: He is with me.

2 BY MS. THOMPSON:

3 Q. Going back to your report, Dr. Bales, on
4 page -- the bottom of Page 7, let's go to Page 7,
5 in the first paragraph, dyspareunia rates were very
6 acceptable. What is an acceptable dyspareunia rate
7 for you following any type of surgery?

8 A. Well, obviously, it would be better
9 certainly for patients not to have dyspareunia, but
10 any -- I guess we all have a different opinion.

11 I'd tell you my opinion would be any
12 type of vaginal surgery we are doing, if we are
13 getting dyspareunia rates under 10 percent, it's
14 probably very acceptable. But again, that's very
15 sort of general, and again, a lot of patients, as
16 we just cited on some of the previous studies,
17 don't remain sexual active. A fair majority of the
18 patients aren't sexual active.

19 But to answer your question, I guess
20 anywhere in the low teens to less than 10 percent
21 would be acceptable for a vaginal surgical
22 procedure like this.

23 Q. And you would agree that there is a
24 likelihood that at least some of those patients who

1 So, there is a scale, of course, but my
2 point was when you are trying to compare and
3 discern whether it's from associated with a
4 hysterectomy or a native tissue repair or a mesh, I
5 think on balance those can be the same. And that
6 was the question you asked me. You didn't ask me
7 is dyspareunia from patient to patient exactly the
8 same.

9 Q. But you answered dyspareunia is
10 dyspareunia.

11 A. Meaning, again, that -- let me clarify
12 that. Dyspareunia needs to be taken seriously, and
13 that's my only point, that when dyspareunia occurs,
14 it's something that if a person has pain with
15 intercourse, we need to take that seriously.

16 So, I don't -- I don't say, oh, it's
17 mild or major. Dyspareunia is a serious problem
18 for a woman, and that's why if you have
19 dyspareunia, it's bad and it's something we will
20 try to correct. That's the point I was trying to
21 make, and I probably didn't answer it very
22 articulately.

23 Q. Dyspareunia may not always be bad; some
24 dyspareunia is very easy to treat, correct?

1 A. Yes, but it's still bad. It may be easy
2 to treat, but it doesn't mean it's not bad.

3 Q. Do women with vaginal atrophy ever have
4 severe, horrific vaginal pain with intercourse?

5 MR. MORIARTY: Object.

6 A. Yes.

7 Q. That cannot be treated easily with local
8 estrogen therapy?

9 A. That's the first thing we do with those
10 patients with atrophic changes, and very often that
11 can solve the problem, but not always.

12 Q. Do you treat women with dyspareunia that
13 don't have a urologic source?

14 A. Yes.

15 Q. You treat women with atrophic vaginitis
16 when that's the only condition they are presenting
17 with?

18 A. Yeah. So, they typically would come see
19 me because maybe they had a kidney stone or they
20 have had a urinary tract infection, and then in
21 taking their history we find out they also have
22 dyspareunia. We do a vaginal exam, and if they
23 have atrophic vaginitis, of course we treat it.

24 That's part of our history-taking and

1 thorough physical exam. There is no urologic cause
2 for dyspareunia. I mean, bladder pain and
3 dyspareunia are slightly distinct, right, so
4 dyspareunia --

5 Q. Or postoperative urologic surgery?

6 A. Correct.

7 Q. So, your opinion that the quality of
8 dyspareunia and vaginal pain that occurs after mesh
9 surgery is no different from that that can occur
10 with other prolapse surgery?

11 A. Yes. It may not be any different at
12 all.

13 Q. And you are ignoring the dozens of
14 articles that would say something differently,
15 correct?

16 MR. MORIARTY: Objection, form. Go
17 ahead. It's argumentative.

18 A. I'm not sure they say anything a whole
19 lot differently. There is papers that cite pain
20 and dyspareunia after any type of vaginal surgeries
21 and stuff; and certainly among those, as you stated
22 earlier, are papers now looking at experiences with
23 vaginal mesh procedures.

24 Q. Can you cite any paper that would

1 support your opinion that the pain associated with
2 vaginal mesh is no different -- and we are
3 considering all the factors, not that just that it
4 occurs. Can you cite any paper that says that pain
5 that occurs after mesh procedure is no different
6 from that occurring with any other native tissue
7 repairs?

8 A. I'm not sure there has been a
9 comparative study, so I can't say that.

10 Q. It doesn't even have to be a comparative
11 study. Has anybody offered an opinion that the
12 mesh pain after mesh surgery is no different when
13 you consider all the factors that we have talked
14 about, the native tissue repairs?

15 MR. MORIARTY: Objection. Go ahead.

16 A. So, if I see a patient who has vaginal
17 pain and fibromyalgias and says she can't get near
18 her husband and she is on the verge of divorce and
19 she is coming to see me because she was told I'm a
20 pelvic floor reconstructive guy and what can I
21 offer her and that woman has never had vaginal mesh
22 surgery, any surgery, and she has horrific
23 dyspareunia that's affecting her marriage, that
24 woman's dyspareunia is no different than a patient

1 who has had mesh and comes in and complains of the
2 exact same pain.

3 Q. How many postmenopausal women do you see
4 with new onset of dyspareunia due to pelvic floor
5 myalgia?

6 A. That would be hard for me to quantitate
7 the number. A fair number.

8 Q. When was the last time you saw someone,
9 new onset, menopausal, pelvic floor myalgia,
10 horrific dyspareunia, in your practice?

11 A. Probably Monday.

12 Q. I would like to see her records.

13 MR. MORIARTY: Motion to strike.

14 Q. You cited the Maher Cochrane reviews on
15 pelvic organ prolapse repairs in your paper?

16 MR. MORIARTY: Are you talking about
17 in his report?

18 MS. THOMPSON: In his report, sorry,
19 in your report, and the Cochrane 2016 review
20 of pelvic organ prolapse, and we can go ahead
21 and mark this.

22 (Bales Exhibit 21 was marked for
23 identification.)

24

1 BY MS. THOMPSON:

2 Q. And I'm just giving you the summary of
3 the review, and let's look at the key results.
4 The Cochrane review 2016 states that overall the
5 quality of the evidence ranged from very low to
6 moderate. The main limitations were poor reporting
7 of study methods, inconsistency and imprecision,
8 correct?

9 MR. MORIARTY: I'm sorry. I hate to
10 stop you. Could you tell me exactly where you
11 are reading? Obviously you are on the last
12 page.

13 MS. THOMPSON: The very last sentence
14 of the last page.

15 MR. MORIARTY: Oh, you are under main
16 results. I thought you said under key
17 results.

18 MS. THOMPSON: That what I was reading
19 was just quality of the evidence on the last
20 page.

21 BY MS. THOMPSON:

22 Q. Did I read that correctly, Dr. Bales?

23 A. Yeah, I'm sorry. I was on Page 2. I
24 was reading under main results.

1 Q. Under quality of the evidence on Page 3,
2 "Overall the quality of evidence ranged from very
3 low to moderate. The main limitations were poor
4 reporting of study methods, inconsistency and
5 imprecision." Did I read that correctly?

6 MR. MORIARTY: I object. I don't know
7 where you are, what you are reading. I don't
8 see a section called quality --

9 MS. THOMPSON: Plain language summary
10 on the very last page.

11 MR. MORIARTY: Okay. So you are on
12 the fourth page of this document under now
13 "Quality of Evidence" at the very end?

14 MS. THOMPSON: That's where I have
15 been the whole time.

16 BY MS. THOMPSON:

17 Q. "Overall, the quality of the evidence
18 ranged from very low to moderate. The main
19 limitations were poor reporting of study methods,
20 inconsistency and imprecision."

21 Did I read that correctly?

22 A. Yes.

23 Q. And did the authors conclude -- I'm back
24 on the previous page on author's conclusions.

1 "The authors conclude that the
2 risk/benefit profile means that transvaginal mesh
3 has limited utility in primary surgery. While it
4 is possible that in women with higher risk of
5 recurrence the benefits may outweigh the risk,
6 there is currently no evidence to support this
7 position."

8 Did I read that correctly?

9 A. You read it perfectly.

10 Q. And in the last paragraph, "In 2011,
11 many transvaginal permanent meshes were voluntarily
12 withdrawn from the market and the newer lightweight
13 transvaginal permanent meshes still available had
14 not been evaluated within an RCT. In the meantime,
15 these newer transvaginal meshes should be utilized
16 under the discretion of the ethics committee."

17 Did I read that correctly?

18 A. Yes. You read it fine.

19 Q. In 2016 the authors of the Cochrane
20 study, with Prolift having been on the market for
21 11 years and Gynemesh on the market for 16 years,
22 are stating that these meshes should only be
23 utilized under the discretion of an ethics
24 committee, correct?

1 MR. MORIARTY: Objection.

2 Q. Is that not what the authors concluded?

3 A. The authors' conclusion says as you read
4 them. They state new or transvaginal meshes should
5 be utilized under the discretion of the ethics
6 committee. That's what's written here. And it's
7 14 years with the Gynemesh, 2002 to 2016, 14 years.

8 Q. What did I say?

9 A. 16.

10 Q. I stand corrected.

11 MR. MORIARTY: And you said like 11 to
12 for ProLift.

13 MS. THOMPSON: Well, it was introduced
14 in 2005, so that would be 11.

15 MR. MORIARTY: And taken off the
16 market in 2012.

17 MS. THOMPSON: I intended to say 11
18 years after it was introduced to the market.

19 If I said 11 years of use, I am mistaken.

20 There are certainly women who have had it for
21 11 years.

22 We will mark this next as 22.

23 (Bales Exhibit 22 was marked for
24 identification.)

1 outcomes" --

2 A. Yes.

3 Q. -- "from these systematic reviews are
4 not as reassuring for the safety and efficacy of
5 transvaginal mesh as data presented from initial
6 case reports published by authors with a financial
7 COI..."

8 That means conflict of interest, right?

9 MR. MORIARTY: Objection, form.

10 A. That's what conflict of interest --

11 Q. Does "COI" mean conflict of interest in
12 this context?

13 A. Yes.

14 Q. "...with the product being evaluated."

15 Did I read that correctly?

16 A. Yes.

17 Q. And then it discusses the FDA 2011
18 transvaginal mesh alert. You are familiar with
19 that document, correct?

20 A. Correct.

21 Q. And it says, "Unfortunately," reading
22 that paragraph that starts, "Unfortunately, much of
23 the current data on POP surgery presented in our
24 systematic reviews fails to allay concerns outlined

1 in the September 2011 FDA transvaginal
2 polypropylene mesh report that found the safety of
3 transvaginal meshes has not been established;
4 depending on the compartment, the efficacy of
5 transvaginal meshes has not been established to be
6 more effective than traditional repairs; vaginal
7 mesh from POP repair should be reclassified from
8 class II to class III to ensure premarket analysis
9 includes a non-mesh control arm; currently marketed
10 vaginal mesh products should undergo premarket
11 evaluation to better explain" --

12 A. Postmarket.

13 Q. Sorry. Thank you.

14 -- "postmarket evaluation to better
15 explain the risk/benefit of mesh versus POP repair
16 without mesh; and safety and efficacy of mesh at
17 sacral colpopexy had been established."

18 Do you disagree with these conclusions
19 made by Maher, the author of the Cochrane reviews
20 on prolapse mesh use?

21 A. Which specific ones? The entire --

22 Q. The ones I just read from this paper.

23 MR. MORIARTY: Objection, form. Go
24 ahead.

1 A. Yeah, I have some disagreements on some
2 of them. I mean, basically, if you want, we can go
3 over them one by one. There is five bullet points.

4 The safety of transvaginal meshes has
5 not been established. Well, there has been a
6 wealth of studies on transvaginal meshes. We have
7 been talking about them in a number of the studies.
8 So, I think the safety has been established, and we
9 could argue about, you know, each of the papers,
10 but there is a lot of data out there, so --

11 Q. So, you disagree, that the safety has
12 been established. You disagree with the authors of
13 this paper and the Cochrane reviews, correct?

14 A. That's a different question. I thought
15 we were talking about this right now.

16 Q. Well, I'm just saying since that's their
17 opinion in this paper, you would disagree with the
18 authors on that point, correct?

19 MR. MORIARTY: Objection, asked and
20 answered.

21 A. Yes. I thought we would go point by
22 point.

23 Q. And so you would disagree with the FDA
24 as well on that point, correct?

1 A. No. I think -- well, the FDA report was
2 from 2011, and I think the FDA report in 2011 just
3 acknowledged that it was still early; and as you
4 know, with that FDA report, it's cited that there
5 is a variety of different complications that we
6 need to be aware of. And to specifically this says
7 the safety has not been established, I mean, yes, I
8 would disagree. If you have a lot of patients and
9 a lot of experience on safety, then to some degree
10 I would disagree; I think it has been established.
11 I think you have studies out there.

12 Q. And do you disagree that depending --
13 the second bullet.

14 A. Well, let's go through it. "Depending
15 on the compartment the efficacy of transvaginal
16 meshes has not been established to be more
17 effective than traditional repairs." I think there
18 is still, you know, better studies that need to
19 occur, but for sure there is conflicting results on
20 the effectiveness and whether transvaginal meshes
21 are better. I would be fine with that, so, and as
22 it says, depending on the compartment there is a
23 lot of factors that, you know, like what specific,
24 whether you are doing rectocele, cystoceles, what

1 have you.

2 Vaginal mesh repairs --

3 Q. Another point. But you will agree with
4 me, there is no studies that establish superiority
5 of vaginal mesh for effectiveness in the posterior
6 or apical compartments?

7 MR. MORIARTY: Objection. Go ahead.

8 A. Yeah, there is not a lot of good head-to
9 head studies that suggest it's superior.

10 Q. Are there any?

11 A. There are studies that suggest it's
12 equivalent.

13 Q. Not superior?

14 A. Not superior. "Vaginal mesh for pelvic
15 organ prolapse repair should be reclassified."
16 Again, I don't -- you know, that's sort of not my
17 area of knowledge base in terms of what goes into
18 the classification scheme, if you will, so I don't
19 have a good opinion on that.

20 "Currently marketed vaginal mesh
21 products should undergo a postmarket evaluation,"
22 that's okay, I mean, but I don't have a strong
23 opinion of that one way or the other.

24 And the last bullet point, "Safety and

1 efficacy of mesh at sacral colpopexy had been
2 established." As we stated, I mean, again, there
3 is a lot of data on sacral colpopexy, so I would
4 agree that has been established, but as I said, I
5 also would agree that the first point, there is at
6 least data now that has established to some degree
7 the safety and efficacy.

8 So, I hope that was clear. I just
9 wanted to make sure you understood sort of --

10 Q. Were there any studies when Prolift was
11 introduced in 2005 establishing safety and efficacy
12 of the device?

13 A. Well, it was a new device, so I'm not
14 aware that again it was being trialed and such,
15 so... .

16 Q. So the answer would be no?

17 A. So, no.

18 Q. And finally, are you familiar with this
19 paper?

20 MS. THOMPSON: And we will mark that
21 as Exhibit 23.

22 (Exhibit 23 was marked for
23 identification.)

1 BY MS. THOMPSON:

2 Q. Are you familiar with this paper titled
3 "Vaginal Mesh Contraction, Definition, Clinical
4 Presentation and Management"?

5 A. Yes.

6 Q. And one of the two authors of this paper
7 is also the author of the Cochrane reviews that you
8 cited in your paper as well?

9 A. Maher.

10 Q. Maher. Is it your opinion that vaginal
11 mesh contraction is not unique to vaginal mesh
12 devices?

13 A. It is not -- say that again.

14 Q. You've given the opinion that the only
15 complication unique to vaginal mesh devices is
16 exposure and erosion, and I'm asking you is vaginal
17 mesh contraction not unique to vaginal mesh
18 devices?

19 A. I guess anything having to do with the
20 mesh itself is unique to the mesh. We could argue
21 about the extent of contracture, if you will. But
22 if the mesh changes at all, it's only going to
23 change if the mesh is present. So, again, I'm not
24 sure that's a complication, but it's a behavior of

1 the mesh. Maybe that's more accurate.

2 Q. Vaginal mesh contraction characterized
3 by severe vaginal pain, aggravated by movement,
4 dyspareunia in all sexually active women and focal
5 tenderness over contracted portions of the mesh on
6 vaginal examination, commonly involving the lateral
7 fixation arms, you have a question about whether
8 that's a complication or not?

9 A. I don't have a question. If the pain
10 exists, I have a question how much is specifically
11 due to contracture, which is what you were just
12 talking about.

13 Q. Well, these authors are reporting
14 vaginal mesh contraction. Do you question their
15 report?

16 A. I mean, their report is their report.

17 Q. And it certainly wasn't included in your
18 expert report, was it?

19 A. It was not.

20 Q. Vaginal mesh contraction characterized
21 by severe vaginal pain, dyspareunia in all women
22 and focal tenderness over contraction. In fact,
23 you say it's not even established that mesh
24 contracts to any clinical significant degree;

1 correct?

2 A. That's what I said.

3 Q. You certainly consider vaginal mesh
4 contraction a significant clinical condition,
5 correct?

6 MR. MORIARTY: Objection. Go ahead.

7 A. I guess that we can argue about how much
8 and how relevant contracture, how much it occurs,
9 how well it's measured, and if that truly is
10 clinically significant. Certainly these authors
11 feel that they felt some of the pain that they are
12 seeing is related to contracture.

13 Q. And you are aware that there are dozens,
14 literally, of articles describing mesh contracture
15 and the clinical symptoms, primarily pain,
16 associated with it, correct?

17 A. I'm aware that both those things exist,
18 and I'm certainly aware that mesh contractures
19 occur, just like mesh contractures occur in
20 inguinal hernias and ventral hernia and whatever,
21 yes.

22 Q. Okay. We are talking about vaginal mesh
23 contractions, right?

24 A. Yes, and I'm aware that they contract a

1 little bit.

2 Q. A little bit?

3 A. Well, I don't think it's certain. It's
4 very unclear how much they contract. It hasn't
5 been -- it's not well-studied, in percentages and
6 things like that. But yes, that we can say it's
7 safe to say vaginal meshes can contract. I will
8 certainly agree to that.

9 Q. Okay. Well, you state in your report,
10 and I'm just questioning whether this is objective
11 and unbiased, that there is no medical literature
12 conclusively establishing that mesh contracts with
13 vaginal use to clinically significant degrees.

14 So, Maher's paper is not conclusive to
15 you that it occurs?

16 MR. MORIARTY: Objection, form. Go
17 ahead.

18 A. Again, there is two different points you
19 are saying there. We are saying that --

20 Q. I first read your statement and then I
21 want to --

22 MR. MORIARTY: Don't cut him off. He
23 needs to answer your question.

24 MS. THOMPSON: I apologize.

1 MR. MORIARTY: If you don't like the
2 answer, you can follow up.

3 MS. THOMPSON: I'm just trying to get
4 through because I have three hours to cover
5 about 12 products.

6 THE WITNESS: It contracts.

7 MR. MORIARTY: Three, I believe.

8 MS. THOMPSON: Anterior, posterior,
9 total, six, seven, eight.

10 MR. MORIARTY: Prolift, Gynemesh PS.

11 MS. THOMPSON: Prolift, anterior,
12 posterior, total, which he said was three
13 different products, Plus M. Well, okay.

14 That's three products that would give me seven
15 hours. Okay. Go ahead.

16 A. That meshes, and we are talking about
17 vaginal meshes, contract, to the extent of their
18 clinical relevance, I guess I'm not -- I'm not --
19 I'm not convinced that we have a good understanding
20 of the clinical relevance.

21 Q. So in the literally dozens of papers
22 that talk about contraction, retraction, shrinkage,
23 you are not convinced that that's a clinically
24 significant condition?

1 A. I'm not convinced that in all those
2 patients it's simply -- it's as simple as saying a
3 little contraction occurred, and that's what's
4 causing all the pain. I think that it's not very
5 well defined. That's my opinion.

6 Q. Okay. The one paper you did out of the
7 literally dozens of papers that discussed this,
8 including the FDA, as a clinically significant
9 condition that is unique to mesh, the one paper you
10 selected to include in your expert report is Dietz.
11 My question is --

12 A. So you are happy with this one, that I
13 included this one?

14 Q. Oh, let's talk about this one.

15 A. Okay. Please.

16 Q. Did you find this paper on your own or
17 were --

18 MR. MORIARTY: Is this marked?

19 MS. THOMPSON: Let's mark that as the
20 exhibit next.

21 (Bales Exhibit 24 was marked for
22 identification.)

23 BY MS. THOMPSON:

24 Q. My question, first of all, is this a

1 paper you found on your own literature search, or
2 was this something that was furnished to you by
3 defense counsel?

4 A. I don't recall. I think I found it on
5 my own.

6 Q. And this is the one you chose out of
7 dozens, if not hundreds, of articles that discuss
8 mesh shrinkage, contraction, retraction and the
9 clinical significance, correct?

10 MR. MORIARTY: Objection, form.

11 A. This is one that's cited in my Herrera
12 report.

13 Q. Let's look at this report from 2011.

14 You are aware that Dr. Dietz is a consultant for
15 mesh manufacturers, correct?

16 A. Yes. Well, I'm just reading it.
17 Actually, I didn't remember that, but I'm reading
18 underneath on the first page here. It says he has
19 acted as a consultant for various vendors, so yes,
20 I guess he is.

21 Q. And Dr. Dietz used translabial
22 ultrasound in this study, correct?

23 A. Correct.

24 Q. Wouldn't that transvaginal ultrasound be

1 A. Oh, I think we are learning more and
2 more. I don't know exactly what the timeframe was
3 on this, but for sure it's newer, right, that we
4 are putting these materials into the vagina, so I
5 think we have an evolving knowledge. I guess that
6 would be more correct to say.

7 Q. When the Prolift was on the market,
8 Gynemesh and Prolift for transvaginal use, was
9 there poor knowledge of the vaginal in vivo
10 response to the materials?

11 A. I think there was limited knowledge.

12 Q. So you take exception with the word
13 "poor" but agree that it was limited?

14 A. I would use the term, yeah, "limited."
15 I wouldn't be comfortable saying "poor." It is
16 limited.

17 Q. Do you agree that the vagina has an
18 important vascularity and endogenous microflora
19 that may have an impact on host tissue response and
20 biomechanical properties of grafts used in pelvic
21 reconstructive?

22 A. Yeah, I agree with that 100 percent.

23 Q. Going to the next page, "What do we
24 observe with mesh repair in our field?" And the

1 statement is "Mesh shrinkage may be associated
2 with," bullet points, "stiffness/tenderness at
3 vaginal examination." Would you agree with that?

4 MR. MORIARTY: Objection, form. Go
5 ahead.

6 Q. Would you agree with mesh shrinkage may
7 be associated with stiffness and tenderness at
8 vaginal examination?

9 MR. MORIARTY: Same objection.

10 A. I guess I would agree. May be
11 associated, I guess I could agree with that
12 statement.

13 Q. Would you agree that mesh shrinkage may
14 be associated with discomfort, pain during
15 intercourse?

16 MR. MORIARTY: Same objection.

17 A. I guess I would just underscore again
18 that I don't know how easy it is to determine
19 whether mesh shrinkage is what's causing discomfort
20 and pain after intercourse, so that's why. So, I
21 guess may, may be associated, sure. I guess I
22 could on balance say that's okay.

23 Q. And you certainly agree that there are
24 many papers where the authors are able to make the

1 connection between the shrinkage, retraction,
2 contraction and pain; you just are not able to,
3 correct?

4 MR. MORIARTY: Objection, form. Go
5 ahead.

6 A. Yes, I'm not able to.

7 Q. Do you agree with the statement mesh
8 shrinkage may be associated with pelvic pain?

9 MR. MORIARTY: Same objection.

10 A. I think it was the same thing we said
11 before. There is -- when patients have pain,
12 specifically the mesh being possibly shrinking or
13 is shrinking, is that the cause of the pain, I
14 guess it can be hard to say. So, that's my only
15 concerning about making that blanket statement.

16 Q. Do you agree or disagree with the
17 statement mesh shrinkage may be associated with
18 urinary or defecatory dysfunctions?

19 MR. MORIARTY: Same objection.

20 A. I -- yeah, I guess I'm not sure if the
21 mesh -- yeah, I guess I'm not prepared to say mesh
22 shrinkage causes urinary or defecatory dysfunction,
23 so no.

24 Q. Do you disagree or agree with the

1 statement mesh shrinkage may be associated with
2 prolapse recurrence?

3 MR. MORIARTY: Form objection. Go
4 ahead.

5 A. I would say that mesh shrinkage or mesh
6 loosening, so yes, I would agree with that, could
7 be associated with prolapse recurrence. I would
8 say yes to that statement.

9 Q. And these authors cite three papers to
10 support the statements that they make on this page
11 of this presentation, correct?

12 A. I guess. I mean, it looks like these
13 are slides, right? I mean, again, it seems to me
14 that maybe this was IUGA, right. It was at a
15 meeting and these are just copies of slides, I
16 think, so these obviously are the papers they cite.
17 I would have to go back through those papers are,
18 but sure, it looks like they are giving those
19 citations.

20 Q. Yeah, and my question was just the
21 authors cite three papers.

22 A. Citations are definitely there.

23 Q. And I'm using the word "presentation" on
24 when we are talking about this document, if that's

1 MS. THOMPSON: No, we don't.

2 (At 12:36 p.m. the deposition was
3 concluded.)

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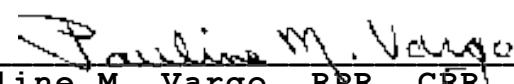
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